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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,269	02/18/2004	Viorica Lopez-Avila	10031188-1	4020

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,269	LOPEZ-AVILA ET AL.	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *19-27 and 31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,28-30 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18 February 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 21 January 2005 is acknowledged. The traversal is on the ground(s) that little, if any, additional searching should be required for the non-elected groups. This is not found persuasive because Applicant has not indicated how and why searching the non-elected groups would not constitute a search burden. Furthermore, each of the groups contain limitations that require searching for material that is not required in the other groups. For example, Group I is a method that requires searching for the step of transferring products to features of a MALDI sample plate, which is not a required search for the other groups. Group II is a system that requires searching for a system that can perform sequential deposition of both sample and agents onto the surface of an array, which is not a required search for the other groups.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18, 28-30, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 1 (line 2), 5 (line 1), and 37 (line 4), the phrase "array of features" is vague and indefinite. Page 9 of the specification defines the term "array", but does not define the term "features" and it is unclear as to what an array of features refers to. Does the term feature refer directly to the "capture agents" (lines 2-3 of claim 1 and line 4 of claim 37), to areas on the array that can contain the capture agents, or to another embodiment?

5. In claim 1, line 4, the term "processing" is vague and indefinite. The specification does not define the term and it is unclear as to what type of processing is involved since the term can imply divergent steps. Does the term refer to analyte isolation, chemical modification, or to another embodiment?

6. In claim 1, line 4, step (b) is vague and indefinite. It is unclear as to how the step of contacting a sample is related to the step of processing any analytes. Are the "analytes" (line 4) related to the "sample" (line 2) of step (a)? As currently written, it is unclear as to whether the analytes and sample have a connection.

7. In claim 1, line 5, the term "features" is vague and indefinite. The specification does not define the term and it is unclear as to what the term refers to. What type of features are claimed on the "MALDI sample plate" (line 5)? Are the features capture agents, physical structures, or another embodiment?

8. In claim 11, line 1, the term "affinity label" is vague and indefinite. The specification does not provide a definition for term and it is unclear what type of material the affinity label is and how it provides binding of the capture agents to the solid support as claimed.

9. In claim 28, line 1, the phrase "a method of claim 12" is vague and indefinite. It is unclear as to which method the phrase refers to. Does the instant phrase refer to one of the steps (a)-(e) in claim 12?

10. In claim 37, line 5, the term "process" is vague and indefinite. The specification does not define the term and it is unclear as to what type of processing is involved since the term can imply divergent steps. Does the term refer to analyte isolation, chemical modification, or to another embodiment?

11. Claim 1 recites the limitation "any products from step (b)" in line 5. There is insufficient antecedent basis for this limitation in the claim. Step (b) of the instant claim

recites the processing of any analytes bound to said capture agents, and does not provide recitation of any products that are formed.

12. Claim 14 recites the limitation "said obtained molecular weights" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 28 recites the limitation "data from a method of claim 12" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-7, 10-15, 17, 18 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Little et al (US 6,387,628 B1).

Little et al reference teaches the immobilization of a polypeptide of interest to a solid support using a pin tool in an array (i.e. contacting a sample), wherein the pin tool has a functional group attached to each pin tip (i.e. array of features). See column 50, lines 2-13. Little et al reference also teaches that a pin tool can be washed with ammonium citrate to condition the polypeptide prior to addition of matrix for identity

determination by mass spectrometry, wherein the mass spectrometry can be MALDI (i.e. processing any analytes bound to said capture agents for MALDI analysis). See column 51, lines 2-7 and column 54, lines 49-51. Little et al reference also teaches the detection of different polypeptides. See column 11, lines 22-35. Since different polypeptides are detected, it is necessarily required that the pin tools contain more than one type of functional group to immobilize the different polypeptides (i.e. array of features containing different capture agents). In addition, Little et al reference teaches that polypeptides can be released or transferred from the pins prior to analysis or cleaved from the pins into a nanowell on a chip prior to addition of matrix, and that the pin tool can pass prepared polypeptide arrays to a plate assembly that disposes the arrays for analysis by mass spectrometry (i.e. transferring any products from step (b) to features of a MALDI sample plate, to prepare said MALDI sample plate). See column 50, lines 60-64; column 51, lines 12-14; and column 52, lines 17-21.

With regards to claims 2-5, Little et al reference teaches that the pins include a jet assembly (i.e. pulse-jet and contact fluid delivery device) and are used to immobilize a polypeptide of interest and can transfer polypeptides from the pins prior to analysis (i.e. employed in steps (a) and (c)) and can be washed to condition the polypeptide prior to addition of matrix (i.e. employed in step (b)), as stated above. See column 50, lines 2-13; column 51, lines 2-7 and 12-14; column 52, line 5; and column 54, lines 49-51.

With regards to claims 6-7, Little et al reference teaches that the pins are on a array surface that can be flat (i.e. planar substrate) and have an interior chamber

capable of driving fluid through the interior chamber (i.e. substrate having fluid retaining structures). See column 51, line 59 and column 52, lines 6-9.

With regards to claims 10-11, Little et al teach that the pins can have antibodies specific for a target polypeptide attached thereto (.e. capture agents are antibodies; comprise an affinity label). See column 50, lines 34-38.

With regards to claim 12, Little et al reference teaches that sample is analyzed by MALDI mass spectrometry (i.e. evaluating said transferred products using a MALDI mass spectrometer to assess said sample), as stated above. See column 54, lines 49-51.

With regards to claims 13 and 17, Little et al reference teaches MALDI mass spectrometric analysis to provide accurate measurement of molecular weight (i.e. determining molecular weights; quantitative). See column 4, lines 2-18, especially lines 2-5 and 16-17.

With regards to claim 14, Little et al reference teaches that identification of the polypeptide is effected by comparison with a reference polypeptide, wherein the molecular mass of peptide fragments of the target polypeptide is compared with the molecular mass of peptide fragments of a corresponding known polypeptide (i.e. comparing said obtained molecular weights to molecular weights of pre-determined analytes). See column 57, lines 30-33 and column 58, lines 10-12.

With regards to claim 15, Little et al reference teaches that the masses of peptide fragments of a corresponding known polypeptide can be obtained from a database of

polypeptide sequence information (i.e. wherein said molecular weights for said pre-determined analytes are in a database). See column 58, lines 12-15 and 19-22.

With regards to claim 18, Little et al reference teaches that the masses of peptide fragments of a corresponding known polypeptide can be determined in parallel reaction with the target polypeptide, wherein the corresponding known polypeptide is also contacted with the agent (i.e. assessing the formation of capture agent/analyte complexes relative to the formation of control capture agent/analyte complexes). See column 58, lines 12-16.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (US 6,387,628 B1) in view of Marshall (US 5,236,826).

Little et al reference has been disclosed above, but fails to teach the step of separating analytes that are bound to said capture agents from those that are not bound to said capture agents.

Marshall reference teaches washing bound and unbound material components, in order to reduce the amount of background noise present by unbound signal generating material remaining in the zone of measurement. See column 5, line 60 to column 6, line 7. Marshall reference also teaches that the components are in a solid phase immunoassay. See column 4, lines 4-8.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Little et al with the step of washing bound and unbound material components, as taught by Marshall, in order to reduce the amount of

background noise present by unbound signal generating material remaining in the zone of measurement. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in washing away unbound material, as taught by Marshall, in the method of Little et al, since Little et al teach a solid phase immunoassay, and the washing step taught by Marshall is performed on a solid phase immunoassay.

20. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (US 6,387,628 B1) in view of Krantz et al (US 5,840,733).

Little et al reference has been disclosed above, but fails to teach the step of drying said transferred products on said MALDI sample plate.

Krantz et al reference teaches that samples for MALDI-MS were mixed on an analysis plate with a matrix and then dried, in order to allow for crystallization and insertion into the instrument for laser ionization. See column 12, lines 44-49.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Little et al with the step wherein samples for MALDI-MS were mixed on an analysis plate with a matrix and then dried, as taught by Krantz et al, in order to allow for crystallization and insertion into the instrument for laser ionization. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in drying the matrix mixture, as taught by Krantz et al, in the method of Little et al, since Little et al teach mixing polypeptide sample with

matrix prior to MALDI mass spectrometry, and the drying step taught by Krantz et al is also performed prior to MALDI mass spectrometry.

21. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (US 6,387,628 B1) in view of El Shami et al (US 6,525,187 B1).

Little et al reference has been disclosed above, but fails to teach that said evaluating is determining amounts of said analytes bound to said capture agents.

El Shami et al reference teaches determining a test amount of an analyte, in order to compare an amount of an analyte in a subject sample to that of a normal amount of analyte from a healthy individual, wherein the analyte is a protein and is detected using MALDI mass spectrometry. See column 13, lines 25-35 and column 43, lines 30-38.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Little et al with the step of determining a test amount of an analyte, as taught by EL Shami et al, in order to compare an amount of an analyte in a subject sample to that of a normal amount of analyte from a healthy individual, wherein the analyte is a protein and is detected using MALDI mass spectrometry. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in determining the amount of analyte, as taught by El Shami et al, in the method of Little et al, since both Little et al and El Shami et al utilize MALDI mass spectrometry for detecting analytes.

22. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (US 6,387,628 B1) in view of Sugiyama (US 6,828,421 B1).

Little et al reference has been disclosed, but fails to teach the step of transmitting data from a first location to a second location, wherein the second location is a remote location, and receiving a transmitted result of a reading of an array.

Sugiyama reference teaches the step of transmitting data in the form of email or posted on a website, wherein the data includes molecular weight information, in order to communicate information to other researchers in a different country. See column 45, line 50 to column 46, line 16.

It would have been obvious to one ordinary skill in the art at the time of the invention to modify the method of Little et al with of transmitting data in the form of email or posted on a website, wherein the data includes molecular weight information, as taught by Sugiyama, in order to communicate information to other researchers in a different country. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in transmitting data by email or internet posting, as taught by Sugiyama, in the method of Little et al, since Little et al teach the identification of target analyte by determining the analyte's molecular weight, and the data transmitted by Sugiyama can include molecular weight information.

Conclusion

23. No claims are allowed.

24. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

Hargreaves (US 4,868,130) teaches solid phase binding assays using beads placed in an array of liquid containing vessels.

Hutchens et al (US 5,719,060; US 5,894,063; US 6,020,208; US 6,027,942; US 6,225,047) teach methods and an apparatus for desorption and ionization of analytes, including MALDI.

Lennon et al (US 6,734,424 B2) teach methods and an apparatus for forming spots in an array using a pipette and fluid transfer between microtiter plates.

Kris et al (US 6,238,869 B1) teach arrays of test regions with different probes specific for a target of interest.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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03/04/05